REMARKS

Reconsideration of this application and allowance of the claims is requested. Claims 1 and 5 have been amended to clarify the invention. It can be seen from Fig. 1 that the branch line 28 is indeed for a connection with a source 40 of physiological, cell free solution and also to a pressure transducer 37.

The examiner has allowed claims 14 and 15.

Claims 16-18 were withdrawn from further consideration as being drawn to a non-elected species. However, since they are dependent on an allowed generic claim 14, they should be put back into the application and allowed along with claim 15.

The examiner has rejected claim 5 as anticipated by Petre U.S. Patent 4,444,198.

When the circulatory monitoring system and method of Petre is compared with claim 5, the examiner is urged to note that Petre fails to disclose "A tubular medical set for the transfer of blood" as called for in claim 5. Rather, Petre monitors blood pressure through an indwelling arterial catheter, having a flush system as part of the Petre device. This is submitted not to comprise a tubular medical set for the transfer of blood, since blood pressure is being measured, and blood is not being transferred from the patient to an extracorporeal blood treatment system or the like, as called for in claim 5.

Furthermore, if the Petre "main blood flow tubing" (using claim 5 language) would be the line 30 that extends from the indwelling arterial catheter 10 to the electronic monitoring equipment 26, then, using the terminology of claim 5, the "flexible branch tube" which is connected in branching relation to the main tubing, would comprise the line that extends from solution bag 12 and incorporates micropassage 15. However, note that such a branch line, while connecting to the solution bag 12, is not a branch

line that connects to pressure transducer 23. To the contrary, in claim 5, the flexible branch tube which is connected in branching relation to the main tubing is...for connection to a source of physiological, cell free solution and to a pressure transducer, and for retaining a blood-solution interface in said branch tubing spaced from the source of solution and the pressure transducer...".

This is clearly seen in Fig. 1 of this application as branch tubing 28, which illustrates a significant structural difference of this invention from Petre et al. The branch tubing 28 comes off of the main blood line which includes pump tubing 44, tubing 20, and tubing 52. The branch tubing 28 branches again, to be connectable to a source of solution 40 and to a pressure transducer 37, while in Petre, it is submitted that no branch line connects with the transducer.

Furthermore, in claim 5, the branch line carries the blood-solution interface 106, and the device to suppress pressure pulses 108, which is a slide clamp as shown in Figs. 5 and 6, having a groove 116 so that the clamp does not completely shut off all communication across the clamp.

The point of maintaining of the blood solution interface in the branch tube is to provide a length of solution in the tube which is blood free, to protect the transducer 37 from contamination by blood. This is provided by maintenance of blood-solution interface 106, which is spaced from transducer 37 and tube 30 by solution in the tube. The pressure pulses come from the rotary pump 46, which, of course, causes oscillatory pressure in the blood line, which pressure is transferred through branch tube 28 to disrupt the blood solution interface 106, except for the presence of slide clamp 108. This clamp greatly constricts the transmission of fluid through tube 28 across the slide

clamp, while slowing down but permitting the transmission of pressure, so that the pressure oscillations are damped, and the blood solution interface 106 is less likely to be disrupted.

When one looks at Petre, there arguably is a "branch tubing" having a micro flush passage 15 which, if there were oscillatory pressure from the indwelling arterial catheter 10, would be damped. Also, there is fast flush valve 16, which would permit rapid transfer of solution from bag 12 to the catheter and the transducer. But, the location of the micro flush passage 15 does nothing to protect the transducer from blood coming from the catheter, and it does nothing to protect a blood solution interface somewhere along the line of the conduit 30 leading to the transducer.

Accordingly, it is submitted that Petre device simply does not render obvious the invention of this application. Furthermore, it can be seen that the language of claim 5: "A tubular medical set for the transfer of blood, said set having main blood flow tubing" is critical and not found in Petre, because blood does not really flow in that device as it flows through pump tubing 44 and conduits 52, 72, and 20, comprising a circulatory system as shown in Fig. 1 for extracorporeal processing of blood, making use of dialyzer 16, for example.

Furthermore, claim 5 requires the flexible branch tube to be "...connected in branching relation to the main tubing for connection to a source of physiological, cell free solution and to a pressure transducer, and for retaining a blood-solution interface in said branch tube..."

In Petre, it is not seen how a blood solution interface would be maintained, especially in the case of oscillatory pressures in the indwelling catheter 10 (although there is no extracorporeal blood pump present in this system).

Furthermore, claim 5 calls for "a device to suppress pressure pulses tending to disrupt said blood-solution interface in said branch tube...".

The branch tube is for connection with the pressure transducer in claim 5. In Petre, the pressure transducer is completely exposed to any pressure pulses that would be present, originating in the arterial catheter, and thus this portion of claim 5 is not met either. A major purpose of this present invention is to provide a portion of solution in the tube which is next to the pressure monitor 37, to protect pressure monitor 37 from contact with blood. Normally, the blood mixes with the solution, eliminating the blood-solution interface 106, so that portions of blood migrate to the vicinity of pressure monitor 37. By this invention, a removable constriction, provided by a clamp 108 as shown in Fig. 1, reduces the impact of the pressure pulses generated by blood pump 46, while still permitting the transfer of pressure per se, so that the pressure monitor 37 can still read an average pressure in the line on a real time basis, but a blood solution interface 106 is maintained, so that blood does not get to the pressure monitor 37. And, clamp 108 can be removed, to remove the constriction and provide fast flow when needed.

From this, it can be seen that Petri simply fails to accomplish the above claim 5, which incorporates the invention, and has clear distinctions over Petre.

The examiner has also rejected claim 1 and many other claims as unpatentable over Petre in view of Dawe U.S. Patent No. 4,519,792.

The examiner claims that Petre teaches all the claimed subject matter, except for allowing back flow. The examiner then states that Dawe teaches the use of back flow-permitting valves.

However, in view of the previous discussion with respect to claim 5, it is submitted that there are very significant differences between Petri and the invention of this application as expressed by claim 5, and also in similar manner by claim 1 (and its dependent claims).

The attention of the examiner is directed to the portion of claim 1 that begins on line 4, which states "...a portion of said branch tube being substantially flattened, whereby said tube portion has a lumen that can reduce its cross-sectional area responsive to negative pressure in the area, to suppress negative pressure pulses tending to disrupt said blood-solution interface, while said tube portion can increase its cross-sectional area responsive to positive pressure in said area to facilitate solution flow therethrough."

This flat portion of the tube is defined by slide clamp 108 as shown in Figs. 1, 5, and 6. Because of the presence of groove 116, slide clamp 108 does not completely shut off flow through tubing 28, but, rather, produces the substantially flattened area in which the cross sectional area of the lumen can be reduced responsive to negative pressure. To substantially increase the cross sectional lumen area for fast fluid flow, the slide clamp can simply be removed. See the specification beginning at the first complete paragraph of page 14 for a description of this, and extending over to page 15.

It is submitted that nothing of this is disclosed in any combination of Petre in view of Dawe. In Petre, there is no valve present that protects the transducer 23 from any

pressure pulses that might come from the indwelling arterial catheter, (although in that particular context, any such pressure pulses would only come from the heartbeat of the patient). The fast flush valve 16 and the micro flush passage 15 are for a completely different purpose, and do not protect the transducer from such pressure pulses.

The fact that Dawe, or any prior art, discloses valves that permit back flow does not add to the weight of the rejection of Petre, which fails to teach the invention of claim 1 for reasons as discussed above, particularly, the failure to teach structure that protects the transducer line from pulsatile pressures, to maintain a blood-solution interface, and the substantially flattened portion of the branch tube, which is capable of reducing its cross sectional area responsive to negative pressure.

Accordingly, it is submitted that claim 1 and its dependent claims are patentable.

The examiner has also rejected claim 4 as unpatentable over Petre in view of Dawe, further in view of Brugger et al. U.S. Patent 5,693,008.

All that Brugger adds to the weight of the rejection is the disclosure of a clamp for the tubing. It is agreed that clamps per se, including slide clamps that are rather similar to clamp 108, are well-known and in widespread clinical use on various types of medical sets. The difference, however, between the slide clamp of this invention and the slide clamp of most or all of the prior art is the presence of the transverse groove 116, which disables the slide clamp so it is not capable of completely shutting off flow in the tube that carries it. Generally, slide clamps are for the purpose of providing complete sealing of a flow line. Here, the sealing is not quite complete. By intent, there is a leak present so that pressure changes can pass through the slide clamp, so that the average

pressure may be measured on a real time basis, while transient pulsations of pressure are diminished.

It is submitted that nothing of this is taught in the combination of references cited by the examiner.

Furthermore, claim 4 shares in the limitations of claim 1, from which it depends.

The examiner has also rejected claim 1 under the doctrine of obviousness-type double patenting over claim 4 of U.S. Patent No. 5,061,365.

The examiner is urged to note that this reference stands as prior art, since it was published in 1991, even though Mr. Utterberg is the inventor. Generally, it is believed that double patenting rejections are not appropriate in that circumstance.

Claim 4 of U.S. Patent No. 5,061,365 covers a plastic pillow having a wall thickness sufficient to permit at least partial collapse upon exposure to internal negative pressure. Other limitations of claim 4 are, of course, found in claim 1, from which it depends. Claim 1 calls for a medical fluid flow set having the plastic pillow connected in line, the plastic pillow comprising "...a single, blow-molded, integral piece with a third port tube communicating with said pillow at a point between said first and second ports, said third port tube extending laterally outwardly from said pillow and turning to define an outer tube and having an axis essentially parallel to said first and second ports..."

It is submitted that this claim simply does not teach the limitations of claim 1, or render it obvious. Claim 1 of this application calls for a tubular medical set, and a flexible branch tube connected in branching relation to the main tubing. It can be seen that branch tube 28 in Fig. 1 of this application connects outwardly from the junction between pump tube 44 and set tubing 20 by means of a connector 24.

It is not seen that connector 24, although supporting a branch tube, fits the description of the plastic pillow 24 of Utterberg 5,061,365. Particularly, the branch line 30 in Utterberg 5,061,365 does not define the right angled turn, and connector 24 of this present application is not the kind of component that can be "blow molded".

Furthermore, there is nothing in claim 1 of Utterberg 5,061,365 like the language of claim 1 of this application stating that the flexible branch tube is "for a connection to a source of a physiological, cell free solution and to a pressure transducer, and for retaining a blood-solution interface..." (emphasis added).

Furthermore, there is no teaching in claim 1 of Utterberg 5,061,365 that the branch tube is substantially flattened "...whereby said tube portion has a lumen that can reduce its cross sectional area responsive to negative pressure in said area..." Keep in mind that the typical clamp completely eliminates the cross-sectional area of the lumen at one point; it does not just reduce it. That is a distinction over the claims of the prior art, including Utterberg 5,061,365.

The examiner has also rejected claim 1 of this application under obviousness type double patenting over claim 3 of Utterberg U.S. Patent 5,520,640.

While claim 3 of Utterberg 5,520,640 describes a flattened plastic tube. The flattened plastic tube comprises a structure which is drastically different from claim 1 of this application. Basically, the flattened plastic tube is the entire blow molded structure such as blood chamber 28 (Fig. 2). See, for example, column 3, lines 27-37 of Utterberg 5,520,640.

Thus, even though claim 1 of this application does claim a blood set with a branch tube, and a flattened, flexible tube, it can be seen from the context of claim 1

how drastically different the two subjects matter defined by the claims are. The flattened plastic tube of patent claim 3 represents the entire blow-molded structure. In claim 1 of this application, only a portion of a branch tube 28 is substantially flattened; specifically that portion which passes through slide clamp 108. Furthermore, the function of this substantially flattened portion, as defined in the last five lines of claim 1, is completely different from that which is defined in patent claim 3, in the light of the parent claims 1 and 2 of Utterberg 5,520,640.

Thus, it is submitted that double patenting does not apply, nor does Utterberg 5,520,640 teach the invention of this application as prior art, although it could be prior art because of its 1996 publication date.

The examiner has also rejected claim 4 under obviousness-type double patenting as unpatentable over the Utterberg U.S. Patents 5,061,365 and 5,520,640, in view of Brugger et al. 5,693,008.

Brugger, and much other prior art, shows slide clamps per se on flexible tubing. The difference of this invention is that the slide clamp has been basically disabled by groove 116, so that it does not completely close the lumen in the tubing, but provides a flattening, and a small leak through the flattened closure. Thus, such a slide clamp can effect the purposes of claim 1, particularly the last five lines, which provides distinction as described above over the references cited by the examiner in this double patenting rejection.

The examiner has also rejected claims 5, 19, 20, 26 and 27 under the obviousness-type double patenting doctrine as unpatentable over claims 1, 4 and 6 of Utterberg et al. Patent No. 6,383,158.

There is a similarity of the inventions here, although Utterberg et al. 6,383,158 could stand as prior art, since the inventorship is different between the two cases. However, the rejected claims of this application are distinctly different from the disclosure and claims of Utterberg et al. 6,383,158.

Utterberg et al. 6,383,158 does show the structure of the first five lines of claim 5 of this application. However, it lacks structure claimed in the subsequent lines, namely "...a device to suppress pressure pulses tending to disrupt said blood-solution interface in said branch tube while allowing the transfer of pressure across said pressure pulse suppression device at essentially at all times and permitting at any time the relatively unrestricted flow of said cell-free solution through said branch tubing to the main blood flow tubing."

Nothing of that is taught in Utterberg et al. 6,383,158, or claimed. For example, there is no clamp like clamp 108 with its transverse groove to prevent complete shut off. Accordingly, claim 5 is patentably distinct over Utterberg et al. 6,383,158, and particularly the method claims 1, 4, and 6 of that patent.

Also, if there is anything constant in Patent and Trademark Office practice, it is the position that a structure claim like claim 5 of this application represents a different invention from method claims. It is regular practice for method claims to be restricted by the PTO from structure claims. Such method claims particularly fail to disclose the critical limitations cited above with respect to claim 5, and clearly cannot render claim 5. Subject to double patenting.

The rejected claim 19 is dependent upon claim 5, and thus shares in its patentable limitations.

Turning to rejected claim 20, it calls for a similar flow restriction device to suppress pressure pulses, but with free, unhindered flow from the branch tube to the main blood flow tubing, per Figs. 11-14, for example. It is submitted that no such device is disclosed in Utterberg et al. 6,383,158, or claimed in the specific claims raised by the examiner. Thus, it is further submitted that claim 20 and dependent claims 26, and 27 are patentable over the examiner's double patenting rejection.

At the bottom of page 4 of the Office Action, the examiner states that Utterberg, et al. 6,383,158 claims a "flow-resisting constriction" (at claim 6).

Claim 5 of this application is also patentably distinct over claim 6 of Utterberg 6,383,158. Claim 6 of Utterberg 6,383,158 calls for "a flow resisting constriction to slow movement of an interface boundary between blood and said aqueous solution in said branch connection tubing upon pressure changes." Claim 5 of this application adds to that the device which suppresses pressure pulses with such a flow restriction while also "...permitting at any time the relatively unrestricted flow of said cell-free solution through said branch tubing to the main blood flow tubing." Claim 20 has related language.

It is submitted that such is not taught or claimed in Utterberg et al. 6,383,158. The Utterberg et al. patent teaches, at column 5, lines 7-21 the concept of placing a "flow-resisting constriction" into the branch tubing. However, there is no teaching of a structure that permits opening of such a flow-restricting constriction, that can be quickly removed so that the tube can be opened wide, as called for in claim 5 and as disclosed herein. It would be time consuming and slow to run solution through the constriction to the patient, and there may be a need for rapid infusion of the solution. That is taught in claims 5 and 20 and also applies to their dependent claims.. It should be added that a

specific embodiment of claim 20 is the intentionally slightly leaking ball valve system of Figs. 11-14. This improvement is clearly not taught or claimed in Utterberg et al. 6,383,158, and it is submitted to be patentably distinct therefrom.

The examiner has also rejected claims 5, 19, 20 and 27 under the obviousness-double patenting doctrine over claims 3 and 4 of Utterberg et al. U.S. Patent No. 6,514,225. Here also, this patent is prior art in view of its earlier filing date and differing inventorship. Also, it is a division of a prior patent 6,383,158.

As before, Utterberg et al. 6,514,225 does teach and claim structure similar to the first five lines of claim 5 of this application. As the examiner says, patent claim 3 teaches a flow resisting constriction to slow movement of an interface boundary between the blood and the aqueous solution of the branch connection tubing upon pressure changes. However, what claim 5 of this application teaches, which is not found in Utterberg et al. 6,514,225 or claimed therein, is the improvement in the device to suppress pressure pulses in that it can permit "...at any time the relatively unrestricted flow of said cell-free solution through said branch tubing to the main blood flow tubing."

In this application, that is accomplished by the removable slide clamp 108, for example, or by use of the intentionally leaking ball valve of Figs. 11-14, and other embodiments. As in the previously discussed patent, a flow-resisting constriction is disclosed in Utterberg et al. 6,514,225 at column 5, lines 12-26. There is, however, no teaching in the patents of a way to permit "...at any time the relatively unrestricted flow of said cell-free solution through said branch tubing..."

Obviously, the presence of a "flow-resisting constriction" as disclosed in Utterberg et al. 6,514,225 will cause restricted flow at all times through the branch tubing. This invention adds to that the improvement of various ways, as claimed in claims 5, 20, and their dependent claims, to have it both ways: a flow resisting restriction of flow from the main blood flow tubing to the branch tube, while permitting substantially free, unhindered flow from the branch tube to the main blood flow tubing (as called for in claim 20). The specific embodiments for how this is done are shown in Figs. 11-14, for example, and in other embodiments such as Figs. 15 and 16.

In view of the above, allowance of the claims is respectfully requested.

Respectfully submitted,

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Date: March 12, 2004